

**REMARKS**

*Claims 1 to 21 are pending in the case. The Examiner has withdrawn claims 22 to 44 from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a non-elected invention. The Applicants have amended claims 1 and 15, to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Support for the present amendments is found throughout the specification and claims, as originally filed. No new matter has been added and no claims fees are believed to be due. The Applicants believe that the present Amendments, and accompanying Remarks, have placed the present application in condition for allowance. Accordingly, timely and favorable action is respectfully requested.*

**BEST AVAILABLE COPY****Rejection under 35 USC § 112, Second Paragraph**

The Examiner has rejected claim 15 under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner asserts that the aforementioned claim recites the phrase "component C)" for which no antecedent basis exists in claim 1, from which claim 15 depends. The Examiner's attention is respectfully directed to the "Amendments" section of the instant paper, in which the Applicants have amended claim 15 to remove the recitation of the aforementioned phrase. Support for the present amendment is found at page 21 of the present specification. In light of the present amendment, reconsideration and withdrawal of the rejection to claim 15 under 35 USC § 112 are respectfully requested.

**Provisional Obviousness-Type Double Patenting**

The Examiner has provisionally rejected claims 1-6, 8, 11 and 13-21 of the present Application under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-15 of co-pending Application No. 09/774,557 (hereinafter "'557"). The Examiner's attention is respectfully directed to the "Amendments" section of the instant paper, in which the Applicants have amended claim 1 of the present application, from which the balance of the rejected claims ultimately depend, to remove H, CH<sub>3</sub> and C<sub>2</sub>H<sub>5</sub> from the definitions of R<sub>3</sub> and R<sub>4</sub> therein. In light of the present amendments, the Applicants wish to note and underscore to the Examiner that '557 fails to teach or suggest the general prostaglandin structure of amended claim 1. The Applicants direct the Examiner's attention to variable "X" of present claim 1 and claim 1 of '557. It is clear that the "X" of present claim 1 is defined to be a saturated hydrocarbon (*i.e.* a carbon-carbon single bond). Conversely, '557 defines "X" as being selected from the group consisting of -C≡C-, a covalent bond, -CH=C=CH-, -CH=CH-, -CH=N-, -C(O)-, -C(O)Y-, -(CH<sub>2</sub>)<sub>n</sub>-, wherein n is 2 to 4, -CH<sub>2</sub>NH-, -CH<sub>2</sub>S-, and -CH<sub>2</sub>O-. Thus, for the general structure of claim 1 of '557 to render obvious the claims of the present invention, '557 would have to define "n" as being equal to 1. However, "n" is explicitly defined in '557 to be "2 to 4." It is therefore impossible for "X" of '557 to be a saturated hydrocarbon. Moreover, the Applicants' amendment to present claim

1, redefining the designations of  $R_3$  and  $R_4$ , removes any possibility of '557 anticipating or rendering obvious the claims of the present invention, even if the "n" of '557 was equal to 1. Accordingly, reconsideration and withdrawal of the provisional obviousness-type double patenting rejection are respectfully requested.

Rejection under 35 USC § 102(b) over Vos

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The Examiner has rejected claims 1-6, 8, 11 and 13-17 under 35 USC § 102(b) as allegedly being anticipated by WO Patent Number 99/12895 to Vos et al (hereinafter "Vos"). The Examiner's rejection is respectfully traversed. The Examiner's attention is respectfully directed to the "Amendments" section of the instant paper, in which the Applicants have amended claim 1, from which the balance of the aforementioned claims ultimately depend, to remove H,  $CH_3$  and  $C_2H_5$  from the definitions of  $R_3$  and  $R_4$  therein. Support for the present amendments is found throughout the specification and claims, as originally filed. In light of the present amendments, the Applicants wish to underscore to the Examiner that Vos fails to anticipate, or even render obvious, the claims of the present invention, as amended. Indeed, there exist several material differences between the general prostaglandin structure of present claim 1 and that of claim 1 of Vos. Initially, it is important to note that the bond connecting the top (alkyl) chain in claim 1 of the present invention is designated as being either alpha ( $\alpha$ ) or beta ( $\beta$ ) whereas Vos clearly defines the same bond to be only alpha ( $\alpha$ ). Additionally, the Applicants wish to note that the bond connecting the  $C_{11}$  (alcohol) position in the prostaglandin structure of present claim 1 is clearly designated as being only alpha ( $\alpha$ ) whereas Vos defines the same bond to be alpha ( $\alpha$ ) or beta ( $\beta$ ).

Moreover, amended claim 1 now defines  $R_3$  and  $R_4$  to be only  $OR^{10}$ ,  $SR^{10}$  and OH whereas Vos defines  $R_3$  and  $R_4$  as being only H,  $CH_3$  and  $C_2H_5$ . Further, Vos defines  $R_{10}$  of claim 1 to be H whereas H is excluded from the present application's definition of  $R_{10}$ . Also, the Applicants wish to note to the distinguished Examiner that present claim 1 defines variable "Y" to be oxygen or a hydrocarbon whereas both such compounds are excluded from Vos' definition of "Y." Finally, and compelling, Vos fails to anticipate the present application's disclosure of a carrier (i.e. Component B), defined on page 19 of the present specification. It is clear then, that the conflicting definitions of variables in Vos prevent the reference from anticipating the claims of the present invention, as amended. Accordingly, reconsideration and withdrawal of the rejection to claims 1-6, 8, 11, 13-17 and 19-21 under 35 USC § 102(b) are respectfully requested.

Rejection under 35 USC § 103(a) over Vos

The Examiner has rejected claims 1-6, 8, 11 and 13-21 under 35 USC § 103(a) as allegedly obvious over Vos. The Examiner's rejection is respectfully traversed. Again, the Applicants wish to direct the Examiner's attention to the "Amendments" section of the instant paper, in which the Applicants have amended claim 1, from which the balance of the aforementioned claims ultimately depend, to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Support for the present amendments is found throughout the present specification and claims, as originally filed. Indeed, the

Applicants wish to renew the arguments provided in the preceding section regarding the imposition of a rejection under 35 USC § 102(b) over Vos. Namely, there exist several, material differences between the claims of the present invention and those of Vos, which prevent a finding of obviousness in the present application. Initially, the Applicants wish to note to the Examiner that the bond connecting the top (alkyl) chain of the general structure in claim 1 of the present application is designated as either being alpha ( $\alpha$ ) or beta ( $\beta$ ) whereas Vos clearly defines the same bond to be only alpha ( $\alpha$ ). Further, the Applicants wish to note that present claim 1 defines the bond connecting the C<sub>11</sub> (alcohol) position of the claimed prostaglandin structure to be only alpha ( $\alpha$ ) whereas Vos defines the same bond to be alpha ( $\alpha$ ) or beta ( $\beta$ ).

The Applicants also wish to direct the Examiner's attention to the Applicants amendment of the definitions of R<sub>3</sub> and R<sub>4</sub> in claim 1. Indeed, amended claim 1 now defines R<sub>3</sub> and R<sub>4</sub> to be only OR<sup>10</sup>, SR<sup>10</sup> and OH whereas Vos defines R<sub>3</sub> and R<sub>4</sub> as being only H, CH<sub>3</sub> and C<sub>2</sub>H<sub>5</sub>. Additionally, Vos defines R<sub>10</sub> of claim 1 as being hydrogen only whereas hydrogen is excluded from the present invention's definition of R<sub>10</sub> in amended claim 1. Moreover, amended claim 1 of the present invention defines "Y" to be oxygen or a hydrocarbon whereas both such designations are excluded from Vos' definition of "Y" in the general structure of claim 1 therein. Finally, and quite compelling, Vos neither teaches nor suggests the present invention's inclusion of a carrier (*i.e.* Component B) in present claim 1, which is defined on page 19 of the present application. In light of the present amendments and preceding argument, the Applicants respectfully submit, and strongly urge, that Vos neither teaches nor suggests the compounds of the present invention. Accordingly, reconsideration and withdrawal of the rejection to claims 1-6, 8, 11 and 13-21 under 35 USC § 103(a) are respectfully requested.

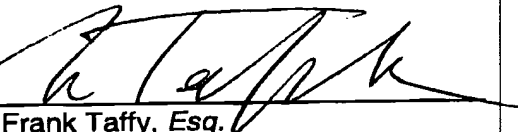
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CONCLUSION

Attached hereto at the conclusion of this communication is a "Version With Markings To Show Changes Made." Applicants have made an earnest effort to place the present claims in condition for allowance. WHEREFORE, entry of the amendments provided herewith, reconsideration of the claims as amended in light of the Remarks provided, withdrawal of the claims rejections, and allowance of claims 1-21, are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicants' undersigned attorney to discuss any remaining issues.

Respectfully submitted,

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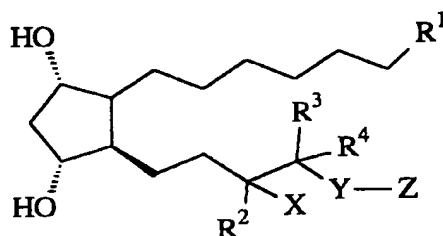
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Claim 1 (amended). A topical composition for treating hair loss comprising:

A) an active ingredient selected from the group consisting of a prostaglandin F analog having the structure



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and pharmaceutically acceptable salts and hydrates of the prostaglandin F analog; biohydrolyzable amides, esters, and imides of the prostaglandin F analog; optical isomers, diastereomers, and enantiomers of the prostaglandin F analog; and combinations thereof;

wherein  $R^1$  is selected from the group consisting of  $CO_2H$ ,  $C(O)NHOH$ ,  $CO_2R^5$ ,  $CH_2OH$ ,  $S(O)_2R^5$ ,  $C(O)NHR^5$ ,  $C(O)NHS(O)_2R^5$ , and tetrazole;

$R^2$  is selected from the group consisting of a hydrogen atom and a lower monovalent hydrocarbon group;

$R^3$  and  $R^4$  are each independently selected from the group consisting of  $H$ ,  $CH_3$ ,  $C_2H_5$ ,  $OR^{10}$ ,  $SR^{10}$ , and  $OH$ ; with the proviso that both  $R^3$  and  $R^4$  are not  $OH$ ;

$R^5$  is selected from the group consisting of monovalent hydrocarbon groups, substituted monovalent hydrocarbon groups, aromatic groups, substituted aromatic groups, carbocyclic groups, substituted carbocyclic groups, heterogeneous groups, substituted heterogeneous groups, heterocyclic groups, substituted heterocyclic groups, heteroaromatic groups, and substituted heteroaromatic groups;

$X$  is selected from the group consisting of  $NR^6R^7$ ,  $OR^8$ ,  $SR^9$ ,  $S(O)R^9$ , and  $S(O)_2R^9$ ;

$R^6$ ,  $R^7$ , and  $R^8$  are each independently selected from the group consisting of hydrogen atoms, acyl groups, monovalent hydrocarbon groups, substituted monovalent hydrocarbon groups, heterogeneous groups, substituted heterogeneous groups, carbocyclic groups, substituted carbocyclic groups, aromatic groups, substituted aromatic groups, heteroaromatic groups, and substituted heteroaromatic groups;

$R^9$  is selected from the group consisting of monovalent hydrocarbon groups, substituted monovalent hydrocarbon groups, heterogeneous groups, substituted heterogeneous groups, carbocyclic groups, substituted carbocyclic groups, heterocyclic groups, substituted heterocyclic groups, aromatic groups, substituted aromatic groups, heteroaromatic groups, and substituted heteroaromatic groups;

$R^{10}$  is selected from the group consisting of a monovalent hydrocarbon group, a substituted monovalent hydrocarbon group, a heterogeneous group, a substituted heterogeneous group, a carbocyclic group, a substituted carbocyclic group, an aromatic

group, a substituted aromatic group, a heteroaromatic group, and a substituted heteroaromatic group; with the proviso that R<sup>10</sup> has 1 to 8 member atoms;

Y is selected from the group consisting of an oxygen atom, a divalent hydrocarbon group, a sulfur-containing moiety, and a nitrogen-containing group; and

Z is selected from the group consisting of a carbocyclic group, a substituted carbocyclic group, a heterocyclic group, a substituted heterocyclic group, an aromatic group, a substituted aromatic group, a heteroaromatic group, and a substituted heteroaromatic group; and

B) a carrier.

Claim 15 (amended). The composition of claim 1, wherein ~~component C)~~component A) is added to the composition in an amount of 1 to 20%, and a sufficient amount of component B) is added such that the amounts of components A), and B), and C) ~~combined combine to~~ equal 100%.

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